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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,186	07/22/2003	Beth A. Lange	KCC 4929 (K-C 18,622)	6849
321	7590	03/09/2005	EXAMINER	
SENNIGER POWERS LEAVITT AND ROEDEL ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			MCCORMICK EWOLDT, SUSAN BETH	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/624,186

Applicant(s)

LANGE ET AL.

Examiner

Susan B. McCormick-Ewoldt

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-102 is/are pending in the application.
- 4a) Of the above claim(s) 1-89 and 97-102 is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 90-96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>December 3, 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election /Restriction

Applicant's election of Group XI and species elections of Sandal complex and *Lactobacillus acidophilus* in the reply filed on January 24, 2005 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-89, 97-102 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species because claims 97-102 contain more than one botanical while Applicant only elected one, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 24, 2005.

Claims Pending

Applicant has withdrawn from consideration claims 1-89, 97-102. Claims 90-96 will be examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 90-96 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The species to which Applicant has elected, Sandal complex, is not defined in the specification. Thus cannot be determined what it is or how to make it. It will be assumed that the term sandal complex is understood as sandalwood and will hereby be examined using sandalwood.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1654

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 90-96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In claims 90 and 93, the term "Sandal complex" is vague and indefinite as to what the Applicant is meaning nor does the specification clearly define the term.

Claims 94 and 96 are rendered indefinite by the use of parenthesis. It is unclear if the enclosed limitations are a required part of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 90-93, 95-96 are rejected under 35 U.S.C. 102(b) as being anticipated by Warren *et al.* (US 6,28,758 B1).

Warren *et al.* (US 6,28,758 B1) expressly teaches a fibrous, absorbent wipe by impregnating an antimicrobial agent, sandalwood, in the amount from .001% to 5% (column 2, line 39-60; column 7, lines 20-24, 28, claim 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 94 is rejected under 35 U.S.C. 103(a) as being unpatentable over Warren *et al.* (US 6,28,758 B1).

The reference is relied upon for the reasons discussed *supra*.

It would clearly have been obvious to one of ordinary skill in the art to administer the wipes as taught by the cited reference because the reference clearly disclose that such preparations is intended to be administered so as to achieve the therapeutic effect beneficially disclosed by the reference. It is known for those skilled in the art that dry wipes are an obvious variant of a wet wipe. The adjustment of particular conventional working conditions (e.g., determining a result-effective amount for a given therapeutic effect taught therein) is deemed merely a matter of judicial selection and routine optimization, which is well within the purview of the skilled artisan.

Thus the invention as a whole is *prima facie* obvious over the reference, especially in the absence of evidence to the contrary.

Variations of components in compositions were well known in the art. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal types of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art. Further, one of ordinary skill in the art would have been motivated to have modified the component in the composition in order to enable the content of the preparation to be matched with the demands and needs of individuals which needed treatment. Such variations in components of pharmaceutically active ingredients are considered merely optimization of result effective variables, conventional practice in the art of pharmacology.

Thus the invention as a whole is *prima facie* obvious over the reference, especially in the absence of evidence to the contrary.

Summary

No claim is allowed.

Art Unit: 1654

Future Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme

Susan D. Coe
3-7-05
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PRIMARY EXAMINER